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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH
1600 TCF TOWER
121 SOUTH EIGHT STREET
MINNEAPOLIS, MN 55402

EXAMINER	
REIDEL, JESSICA L	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,856	KRIG ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-7,9,10 and 12-23* is/are rejected.

7)☒ Claim(s) *4,8,11 and 18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 November 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on October 13, 2004 has been acknowledged and is being considered by the examiner.

Drawings

2. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings appear to be informal. Specifically, Fig. 5 is illegible. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the method further comprising "measuring a temperature of the implantable medical device, comparing the measured temperature to a temperature threshold and discounting the measured battery voltage if the measured temperature is below the temperature threshold" must be shown or the feature(s) canceled from the claim(s). In addition the "first, second, third and fourth memory storage locations" and the "averaging circuit" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The abstract of the disclosure is objected to because the phrase "This document discusses" is present in the first line of the claim. Also, the Examiner suggests changing all instances of "is provided" or "is also provided" to something similar to "is provided to a user" or "is provided to an external device". Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities: the "Cross Reference to Related Applications" needs to be updated to reflect the current status of the listed

Applications. For example, reference to Serial No. 10/395,983 should also include the issued patent number. Appropriate correction is required.

6. The disclosure is objected to because of the following informalities: there appears to be a typographical error at page 7, lines 3. The Examiner suggests changing "the battery terminal voltage to droop" to "the battery terminal voltage to drop". Appropriate correction is required.

Claim Objections

7. Claims 4 and 8 are objected to because of the following informalities: there appears to be a typographical error in the fourth and fifth line of the claim, which makes the claim confusing. The Examiner suggests changing lines 4-5 of the claim to "establishing a value of the current threshold based on whether the implantable device is in the shipping state or is instead in the implanted state". Appropriate correction is required.

8. Claims 5 and 9 are objected to under 35 CFR 1.75(b) because of the following informalities: more than one claim is presented that do not differ substantially from each other and are unduly multiplied. Appropriate correction is required.

9. Claim 11 is objected to because of the following informalities: there appears to be a typographical error in the fifth line of the claim, which makes the claim confusing. The Examiner suggests changing the last line of the claim to read, "comparison of the average measured current delivered by the battery". Appropriate correction is required.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-2, 5-6, 9-10, 12-16, 19-20 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mann (U.S. 5,800,472) and Gurewitsch (U.S. 6,400,988). As to Claims 1-2, 5-6, 9 and 13-14, Mann discloses an implantable pacemaker 10 comprising a control system 86 that includes a microprocessor, read as a computer readable medium (see Mann column 4, lines 9-11) for carrying out a method comprising measuring a terminal voltage V_{BAT} on a POWER signal line or power bus 95 of a battery 93 via monitoring circuits within a control system 86 or elsewhere within an implantable pacemaker 10 (see Mann column 5, lines 25-29 and column 8, lines 49-53), comparing the measured terminal voltage V_{BAT} to a selected one of a plurality of recommended replacement time (RRT) threshold voltages (see Mann column 8, lines 53-59) and as soon as the terminal voltage V_{BAT} drops below the selected one of a plurality of RRT threshold voltages, setting a RRT trigger, read as an indication that may be uploaded to an external programmer 108 via telemetry/communications circuit 104 (see Mann Abstract, column 5, lines 5-23 and column 6, lines 10-19). The Examiner takes the position that that state of operation of the pacemaker 10 (i.e. RRT trigger set or not) is communicated to a user because Mann discloses that the control parameters may be stored in a memory circuit 100 and anything stored in such memory circuit 100 may be telemetered out to an external programmer 108 via communication link 110 (see Mann column 4, lines 38-47 and column 5, lines 17-23).

Mann further discloses that the selected RRT threshold voltage is a function of a rate at which the charge is delivered by the battery 93 by way of the following: when the pacemaker 10 is not operating in a rate-responsive mode (i.e. the rate at which charge is delivered by the battery is low) the RRT threshold voltage is selected to be a normal RRT threshold voltage VO_{RRT}, read as a first voltage threshold and when the pacemaker is operating in a rate-responsive mode (i.e. the rate at which charge is delivered by the battery is high) the RRT threshold voltage is selected to be a lower RRT threshold voltage $V1_{RRT}$, read as a second voltage threshold. Mann further discloses that when the measured terminal voltage V_{BAT} falls below either the first voltage threshold or the second voltage threshold, the RRT criterion for operation is met and the functionality of the pacemaker 10 is altered by increasing the base rate interval by a prescribed amount (see Mann column 5, lines 32-36, column 7, lines 50-67 and column 8, lines 30-33).

Mann also discloses that battery current, read as charge delivered by the battery 93 may be measured and stored in similar fashion as the terminal voltage V_{BAT} (see Mann column 7, lines 43-45 and column 12, lines 64-67). Mann discloses the claimed invention as discussed above except that the method does not include calculation of an available or depleted battery charge using the measured charge delivered by the battery during a first time period and communicating to a user an indication of the available or depleted battery charge.

Gurewitsch, however, teaches that tolerances in battery voltage measurements have too wide a variance to provide an adequate time margin for replacement after an indication of RRT and discloses a method for precise RRT and "end of life" (EOL) indications for a depleteable power source (i.e. a battery 43) in an implantable cardiac device 20 where the indications are based upon the actual remaining energy of the depletable power source (see Gurewitsch

Abstract). Gurewitsch discloses that the method comprises measuring the amount of current provided by the battery 43 is constantly measured by a current monitor 45 to derive a first average current, provided by the battery 43 since its initial hook-up or "beginning of life" (BOL), read as a first time period and a second average current provided over the last 24-hour period, read as a second time period (see Gurewitsch column 1, lines 59-67 and column 4, lines 20-35) and calculating the remaining energy capacity of the battery 43 using the measured current delivered by the battery 43 during the previous 24 hour period. Gurewitsch discloses that multiplying the first average current by the time since BOL to derive actual used capacity and then subtracting the actual used capacity from the initial capacity of the power source determines the remaining energy (see Gurewitsch column 2, lines 1-5). Gurewitsch further discloses that an EOL date, read as an indication of the available or depleted battery 43 is then calculated (see Gurewitsch Fig. 3, column 2, lines 5-11 and column 7, lines 18-65) and communicated to a user via a telemetry/communications circuit 104 (see Gurewitsch Abstract, column 5, lines 54-67 and column 6, lines 1-9).

The Examiner considers the device and method of Gurewitsch to be synonymous with those of Mann since both are concerned with accurately determining the RRT of and implantable medical device, both are capable of measuring charge (i.e. current) delivered by a battery of an implantable medical device and both communicate with an external programming device via a telemetry communications link. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Mann in view of Gurewitsch to include calculating an available or depleted battery charge using the measured charge delivered by the battery and communicating an indication of such to a user to provide an

adequate time margin for replacement after an indication of RRT without relying on variable battery voltage measurements alone.

12. As to Claim 10, the previously modified Mann reference discloses the claimed invention as discussed above except that averaging the measured current does not include averaging over a second time period of about one week. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the method of Mann in view of Gurewitsch, because Applicant has not disclosed that averaging the measured current over a second time period of about one week provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the averaging of measured current being averaged over a second time period of about one day as taught by Mann in view of Gurewitsch, because it provides a means for calculating an EOL date using the most recent average current provided by the battery and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Mann in view of Gurewitsch.

Therefore, it would have been an obvious matter of design choice to modify Mann in view of Gurewitsch to obtain the invention as specified in the claim(s).

13. As to Claims 15-16, 19, 22 and 23, Mann discloses a system comprising an implantable pacemaker 10 which comprises a battery 93 and a monitoring circuit, read as battery terminal voltage measurement circuit coupled to the battery 93 for measuring a terminal voltage V_{BAT} on a POWER signal line or power bus 95 of a battery 93 (see Mann Figs. 1-2, column 5, lines 24-31 and column 8, lines 49-53). Mann further discloses that battery current, read as charge delivered by the battery 93 may be measured and stored in similar fashion as the terminal voltage V_{BAT}

(see Mann column 7, lines 43-45 and column 12, lines 64-67). It is inherent that the monitoring circuit also comprises a battery charge delivery measurement circuit to accomplish this function. The implantable pacemaker 10 of Mann further comprises a control system, read controller circuit 86 coupled to the battery measurement circuit (of the monitoring circuit) to receive information about the measured battery terminal voltage and the battery charge delivery measurement circuit (also of the monitoring circuit) to receive information about a rate at which charge is delivered from the battery (see Mann column 4, lines 9-11 and lines 39-67, column 5, lines 24-36 and column 7, lines 31-49).

Mann further discloses that the selected RRT threshold voltage is a function of a rate at which the charge is delivered by the battery 93 by way of the following: when the pacemaker 10 is not operating in a rate-responsive mode (i.e. the rate at which charge is delivered by the battery is low) the RRT threshold voltage is selected to be a normal RRT threshold voltage VO_{RRT}, read as a first voltage threshold and when the pacemaker is operating in a rate-responsive mode (i.e. the rate at which charge is delivered by the battery is high) the RRT threshold voltage is selected to be a lower RRT threshold voltage $V1_{RRT}$, read as a second voltage threshold. Mann further discloses that when the measured terminal voltage V_{BAT} falls below either the first voltage threshold or the second voltage threshold, the RRT criterion for operation is met and the functionality of the pacemaker 10 is altered by increasing the base rate interval by a prescribed amount (see Mann column 5, lines 32-36, column 7, lines 50-67 and column 8, lines 30-33).

The Examiner takes the position that that state of operation of the pacemaker 10 (i.e. RRT trigger set or not) is communicated to a user because Mann discloses that the control parameters may be stored in a memory circuit 100 and anything stored in such memory circuit

100 may be telemetered out to an external programmer 108 via communication link 110 (see Mann column 4, lines 38-47 and column 5, lines 17-23). Mann also discloses that battery current, read as charge delivered by the battery 93 may be measured and stored in similar fashion as the terminal voltage V_{BAT} (see Mann column 7, lines 43-45 and column 12, lines 64-67). Mann discloses the claimed invention as discussed above except that the method does not include calculation of an available or depleted battery charge using the measured charge delivered by the battery during a first time period and communicating to a user an indication of the available or depleted battery charge.

Gurewitsch, however, teaches that tolerances in battery voltage measurements have too wide a variance to provide an adequate time margin for replacement after an indication of RRT and discloses a method for precise RRT and "end of life" (EOL) indications for a depleteable power source (i.e. a battery 43) in an implantable cardiac device 20 where the indications are based upon the actual remaining energy of the depletable power source (see Gurewitsch Abstract). Gurewitsch discloses that the method comprises measuring the amount of current provided by the battery 43 is constantly measured by a current monitor 45 to derive a first average current, provided by the battery 43 since its initial hook-up or "beginning of life" (BOL), read as a first time period and a second average current provided over the last 24-hour period, read as a second time period (see Gurewitsch column 1, lines 59-67 and column 4, lines 20-35) and calculating the remaining energy capacity of the battery 43 using the measured current delivered by the battery 43 during the previous 24 hour period. Gurewitsch discloses that multiplying the first average current by the time since BOL to derive actual used capacity and then subtracting the actual used capacity from the initial capacity of the power source determines

the remaining energy (see Gurewitsch column 2, lines 1-5). Gurewitsch further discloses that an EOL date, read as an indication of the available or depleted battery 43 is then calculated (see Gurewitsch Fig. 3, column 2, lines 5-11 and column 7, lines 18-65) and communicated to a user via a telemetry/communications circuit 104 (see Gurewitsch Abstract, column 5, lines 54-67 and column 6, lines 1-9).

The Examiner considers the device and method of Gurewitsch to be synonymous with those of Mann since both are concerned with accurately determining the RRT of and implantable medical device, both are capable of measuring charge (i.e. current) delivered by a battery of an implantable medical device and both communicate with an external programming device via a telemetry communications link. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Mann in view of Gurewitsch to include calculating an available or depleted battery charge using the measured charge delivered by the battery and communicating an indication of such to a user to provide an adequate time margin for replacement after an indication of RRT without relying on variable battery voltage measurements alone.

14. As to Claims 12 and 20, the previously modified Mann reference discloses the claimed invention except that the method does not further comprises measuring a temperature of the implantable medical device using a temperature sensor, comparing the measured temperature to a temperature threshold and discounting the measured battery voltage if the measured temperature is below the temperature threshold. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Mann in view of Gurewitsch to comprise measuring a temperature, comparing the temperature to a threshold and

if the temperature falls below a threshold discounting the measured battery voltage since it was known in the battery art that the terminal voltage of a battery seemingly drops when the battery is subjected to very low temperatures even if the actual battery capacity has not actually been depleted.

15. Claims 3, 7 and 17 rejected under 35 U.S.C. 103(a) as being unpatentable over Mann in view of Gurewitsch as applied to claims 1, 6 and 15 above, and further in view of Barreras et al. (U.S. 4,556,061) (herein Barreras). The previously modified Mann reference discloses the claimed invention as discussed above except that the measured current delivered by the battery is not compared to a current threshold where if the measured current exceeds the current threshold then a fault is declared and an indication of the declared fault is not communicated to a user.

Barreras, however, discloses a cardiac pacer with a battery consumption monitoring circuit, which measures current and comprises an over-current alarm 37, which provides an alarm in the event that the current through sensing register 31 exceeds a predetermined maximum level. Barreras further discloses that the over-current alarm 37 continuously compares the amplified sensing signal from the amplifier 32 against an internally provided reference corresponding to the current limit, and in the event of a comparison provides the alarm output signal. The alarm of Barreras may take the form of a variation in pacing rate, in which case the alarm output is connected to pulse control logic circuit 23 or alternatively, the over-current alarm may take the form of an implanted device that vibrates to alert the patient, read as communicating an indication of whether a current fault has been declared. Specifically, Barreras discloses that with either response the patient is alerted to the over-current condition, and the probable malfunction of the pacer circuitry (see Barreras Abstract, column 3, lines 35-68 and

column 1, lines 1-10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Mann in view of Gurewitsch and Barreras to provide means for comparing a measured current to a current threshold and if the measured current exceeds the current threshold, then a fault is declared and an indication of the declared fault is communicated to a user to alert the patient that the device is not functioning properly and to better the invention.

16. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mann in view of Gurewitsch as applied to claim 15 above, and further in view of Er (U.S. 6,185,461). Applicant differs from the previously modified Mann reference in that the system further comprises a user interface including a display, the display including a display meter indicative of battery charge status and an indication of whether the measured voltage is below a first voltage threshold. The Examiner considers the use of such a display and user interface with an external programming device for allowing a physician to monitor/modify the internal battery condition and RRT mode to be conventional and well known in the art with Er being but one example (see Er Fig. 1, Abstract, column 1, lines 49-66 and column 7, lines 48-66).

Allowable Subject Matter

17. Claims 4, 8 and 11 would be allowable if rewritten to overcome the Claim Objections, set forth in this Office Action and to include all of the limitations of the base claim and any intervening claims.

18. Claim 18 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kroll (U.S. 5,925,068) discloses a method of indicating RRT by using both measured battery voltage and measured time it takes to charge a capacitor by the battery as two battery strength indicators for assessing remaining battery life.

Gielen (U.S. 2003/0204219) measures the voltage and/or current of a power supply, compares the measured parameter level to a preselected threshold and if the measured parameter exceeds the threshold, the operational parameters of the device are altered.

Loch (U.S. 6,940,255) uses measured battery voltage and measured load current to calculate an impedance of the battery that is then used with a look-up table to determine the remaining battery capacity.

Rosenquist et al. (U.S. 6,768,288) discloses a method to more accurately monitor remaining battery life under varying load conditions in which the measured battery voltage is adjusted for the current load and then used to determine the remaining battery life according to the battery voltage discharge curve for the battery type and chemistry.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 7-4:30 and every other Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica L. Reidel 08/18/06
Examiner
Art Unit 3766

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766